STERIS®

510(k) Summary
For
Amsco® V-PRO™ 1, V-PRO™ 1 Plus and V-PRO™ maX
Low Temperature Sterilization Systems

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Submission Date: November 3, 2011

1. Device Name

Trade Name:	Amsco V-PRO 1 Low Temperature Sterilization System and Amsco V-PRO 1 Plus Low Temperature Sterilization System and V-PRO maX Low Temperature Sterilization System
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
Classification Number:	21 CFR 880.6860
Product Code:	MLR

2. Predicate Device

Amsco® V-PRO™ 1 Low Temperature Sterilization System (K062297)

Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System (K083097)

Amsco® V-PRO™ maX Low Temperature Sterilization System (K102330)

3. Description of Device

The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilizers are self-contained stand-alone devices using vaporized hydrogen peroxide. These devices are intended for use in terminal sterilization of cleaned, rinsed and dried, reusable medical devices used in healthcare facilities. The sterilizers operate at low pressure and low temperature and are therefore suitable for processing medical devices sensitive to heat and moisture.

4. Intended Use

The Amsco V-PRO MAX Low Temperature Sterilization System, with VAPROX™ HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The three pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The Amsco V-PRO MAX Low Temperature Sterilizer System's **Lumen Cycle**, cleared under K062297, can sterilize:[a]

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including rigid endoscopes, with a single stainless steel lumen with:
  - an inside diameter of 1 mm or larger and a length of 125 mm or shorter
  - an insider diameter of 2 mm or larger and a length of 250 mm or shorter
  - an inside diameter of 3 mm or larger and a length of 400 mm or shorter

[a] The validation testing for all lumen sizes was conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Non Lumen Cycle,** cleared under K083097, can sterilize:[b]

Non-lumened instruments including non-lumened rigid endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

[b] The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Flexible Cycle,** the subject of this submission, can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical care) and bronchoscopes in either of two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c]

   The flexible endoscopes may contain either:
   - a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
   - or two lumens with:
     - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
     - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

   [c] The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d]

   The flexible endoscope can contain either:
   - a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
   - or two lumens with:
     - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
     - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

[d] The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

5. Description of Safety and Substantial Equivalence

The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems are the same as the predicate devices (K062297, K083097 and K102330). Modifications are proposed to the VAPROX® HC Sterilant cartridge/cup, specifically to the design and the material of the cartridge.

The following performance testing has been completed, verifying that the modified product is substantially equivalent to the predicates. The proposed modifications described have introduced no new concerns of safety or effectiveness compared to the predicates.

Device Modification	Testing	Acceptance Criteria	Results
Sterilant cartridge materials change **Sterilant cartridge design change**	Testing at time 0 and 3 months to demonstrate no difference between resins used in construction of the cartridge or current or the current and proposed cartridge design.	No difference in the following characteristics at the 0 time point and following 3 months of storage: • Package Appearance • Sterilant Color • Clarity • Hydrogen Peroxide Concentration • Sterilant pH	**PASS** Testing demonstrates that cups meet 0 time point and stability specifications at 3 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 1 2011

Mr. Robert Sullivan
Senior Director, FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
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Re: K112813
Trade/Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization Systems
Amsco® V-PRO™ maX Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: November 3, 2011
Received: November 4, 2011

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System
Amsco® V-PRO™ maX Low Temperature Sterilization System

Indications For Use:

The Amsco® V-PRO™ MAX Low Temperature Sterilization System, with VAPROX™ HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The three pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Lumen Cycle**, cleared under K062297, can sterilize:[a]

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including rigid endoscopes, with a single stainless steel lumen with:
  - an inside diameter of 1 mm or larger and a length of 125 mm or shorter
  - an insider diameter of 2 mm or larger and a length of 250 mm or shorter
  - an inside diameter of 3 mm or larger and a length of 400 mm or shorter

[a] The validation testing for all lumen sizes was conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Non Lumen Cycle,** cleared under K083097, can sterilize:[b]

Non-lumened instruments including non-lumened rigid endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

[b] The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Flexible Cycle,** the subject of this submission, can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c]

   The flexible endoscopes may contain either:
   - a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
   - or two lumens with:
     - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
     - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

   [c] The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d]

   The flexible endoscope can contain either:
   - a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
   - or two lumens with:
     - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
     - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

   [d] The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

The parameters for the three V-PRO Cycles are as follows:

Sterilization Cycle	Sterilant injection (g)	# of Injections	Sterilant Exposure Time (min)	Chamber Pressure Prior to Injection (Torr)	Chamber/ Vaporizer Temperature (°C)
Lumen	2.1	4	32	0.4	50/60
Non Lumen	2.1	4	12	1	50/60
Flexible	2.1	4	12	0.4	50/60

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K112813